

**REMARKS**

The Office Action dated August 27, 2004 has been carefully considered. In response to the objections to the drawings, Figure 15C has been revised to show window 462. Applicant respectfully requests reconsideration with regard to the objection to the drawings regarding the ends of the splines moving toward each other causing expansion of the spline to the expanded configuration. It is believed that this feature is plainly shown in Figures 3A and 3B. Applicant also requests reconsideration of the objection to the drawings with regard to the introduction of instruments through the lumen of the sheath and the preliminary procedures recited in claim 31. These uses of the device described and illustrated in the present application are, while believed to be patentable in the context of the use of Applicant's device, uses that would be readily understood by one skilled in the art and illustration of them would complicate the drawings such that the drawings would be less useful to the public in understanding the present invention. Thus, it is respectfully requested that the latter objection regarding the introduction of instruments of preliminary procedures be withdrawn.

With regard to the claim objections, claims 41, 46 and 57 have been amended in a manner which is believed to remove the basis for the Examiner's objections.

With regard to the objection to the specification, Applicant respectfully requests reconsideration. The feature of the invention regarding the ends of the splines of the locator moving towards each other causing the expansion of the splines to the expanded configuration is plainly shown, as noted above, in Figures 3A and 3B and is specifically described at page 22, line 19 to page 23, line 2. In pertinent part, this disclosure states:

“The second end 64b may be axially movable to the first end 64a to cause an intermediate region 64c of the spline 64 to expand transversely outward, thereby defining the substantially transverse expanded configuration.”

Thus, it is believed that this objection to the specification should be withdrawn.

Claims 11, 14, 27, 28, 40 42 47 48 51 56-58 and 60-62 have been rejected as anticipated by Green EP 0774237 and claims 29-31, 41, 49 and 50 have been rejected as obvious over that reference. It is respectfully submitted that the rejected claims are neither anticipated by nor obvious over the Green reference. Before turning to the claims themselves, it is believed important to point out that the device of the Green patent:

1. does not have a locator member having a deflectable element which buckles. Rather, the locator element of Green is a two-pronged element which is held under constraint by cannula 100.
2. when the locator member 60 of Green is pushed distally, the constraint is removed and the locator member expands. Green does not actuate his locator member by proximal movement of a control member.
3. As shown in Figure 22 of Green, the clip of Green pinches the wall of the blood vessel lumen in an attempt to close a puncture. The clip of Green does not have tines.

The rejected claims will be discussed in groups. It is, however, to be understood that different claims in each group contain limitations which are entitled to independent consideration

as a basis for patentability ie, the claims in each group are to be considered individually and do not stand or fall as a group.

**Claims 11, 14, 57 and 58**

Claim 11 is an apparatus claim which recited that the control element is movable axially for “causing an intermediate portion of the deflectable element to buckle substantially transversely with respect to the longitudinal axis.” It is respectfully submitted that the expansion of the locator element of 60 of Green when its constraint is removed cannot be properly characterized as buckling. “Buckle” is defined in Random House Webster’s College Dictionary (1991), page 177 in pertinent part, as follows: “to bend, warp, bulge, or collapse.” Stated more simply, something buckles when it changes form when stress is applied to it such that there is a partial or total loss of its original shape by reason of the imposition of a force. This is a precise opposite of the removal of constraint in which shape change is caused by the removal of force rather than the application of force. Thus, it is respectfully submitted that claim 11 is patentable over Green for this reason alone. In addition, claim 11 recited that it is “an intermediate portion” of the deflectable element which buckles. The locator element 60 of Green does not have an intermediate portion which selectively changes shape. Rather, the entire locator element 60 of Green simply expands into a loop.

Claim 14 is patentable for the additional reason that it recites that the actuator is configured for “moving the control element proximally.” The examiner has taken the view that control rod 68 of Green corresponds to the control element recited in the claims. The control rod

68 of Green is moved distally to push the locator element 60 of Green out of cannula 100 to remove the constraint from the support means thereby permitting it to expand. This is precisely the opposite of the proximal movement of the control element as recited in Claim 14. Thus, it is believed that Claim 14 is patentable for this additional reason.

Claims 57 and 58 which are dependent directly or indirectly on claim 11, further recite that the deflectable element comprises one or more splines and that the movement of the control element causes the ends of the splines to move towards each other. No such device is disclosed or suggested by Green. Green has no splines and Green does not cause expansion by moving the ends of his locator element towards each other. Thus, it is believed that claims 57 and 58 are patentable for these additional reasons.

**Claims 27-31 and 60-62.**

These are method claims. Claim 27 which recites the step of "buckling a deflectable element" is patentable because the use of the Green device does not involve buckling, i.e., causing a shape change by imposing force which causes buckling, but rather discloses only the removal of a constraint to permit expansion. Claims 28-31 are patentable for the same reasons as claim 27.

Claims 60-62 recites that the clip is generally annular and has tines which extend substantially axially and distally and are carried on an exterior of the elongate member. None of these features are disclosed by Green. The clip of Green does not have tines and the clip of

Green does not penetrate tissue adjacent to the body lumen as recited in these claims. Thus, these claims are patentable for these additional reasons.

#### **Claims 40-42**

These are method claims and claim 40 is patentable because it recites the step of “buckling a deflectable element” as explained with regard to claim 27. Claims 41 and 42 are patentable for the same reason as claim 40.

#### **Claims 47-51 and 56**

Claim 47 recites the step of “bucking a deflectable element” and the step of advancing a clip having *tines* which extend substantially axially and distally along the locator member. As explained above, the Green reference does not disclose either of these features. Thus, claim 47 is patentable for these reasons alone. Claims 48-51 and 56 are patentable for the same reasons as claim 47.

#### **New Claims 63-67 and 79**

These are apparatus claims and claim 63 is patentable because it recites that the control element is movable axially for “causing an intermediate portion of the deflectable element to buckle substantially transversely with respect to the longitudinal axis” as explained with regard to claim 11. Claims 64 and 66-67, which depend directly from claim 63, are patentable for the same reasons as claim 63. Claim 65 is patentable for the additional reason that it recites that the

actuator is configured for “moving the control element proximally” as explained with regard to claim 14.

Claim 79 is independent and recites that the control element is movable axially for “causing an intermediate portion of the deflectable element to buckle substantially transversely with respect to the longitudinal axis,” that the actuator is configured for “moving the control element proximally” and that the deflectable element comprises one or more splines and that the movement of the control element causes the ends of the splines to move towards each other. Thus, it is believed that claim 79 is patentable as explained with regard to claims 11, 14 and 57.

#### **NewClaims 68-78**

These are method claims and claims 68 and 77 are patentable because they recite the step of “buckling a deflectable element” as explained with regard to claim 27. Claims 69-67 and 78 are patentable for the same reason as claims 68 and 77.

#### **Summary**

There is a fundamental difference between the present application and the disclosure of the Green reference, which is that the actuation of the locator device of the present invention is accomplished by applying force to cause buckling whereas actuation of the locator device of Green is caused by the removal of a constraining force. Thus, Green cannot anticipate any of the claims in this application and there is absolutely no disclosure or suggestion in Green in applying a force to cause buckling. Just the opposite, Green teaches away from applying force by


disclosing the use of the removal of force and nothing else. Thus, none of the claims in the present application can be considered obvious in view of Green.

It is believed that this application is now in condition for allowance. A favorable action is respectfully solicited.

Respectfully submitted,

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